VALIDATION RESULTS FOR METHOD NO. Covance Harrogate 2001-056-D1						
		MEAN	RELATIVE STD. DEV.(%)	RANGE	SEE (conc)	
ANALYTE	MDA					
MATRIX	Human u[illegible]e					
DATE	15-Aug-01					
LLOQ	[illegible]	0.4 µmol/L. Accuracy 112.5%. RSD 6.9%				
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units)						
(SEE = S.D./SQRT (# of determinations))						
	1 µmol/L	Low QC			0.013	
	4 µmol/L	Med QC			0.031	
	8 µmol/L	High QC			0.068	
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE						
Function (Linear, Quatradtic, etc.)	Linear					
Slope (mean)	34850					
Intercept (mean)	-4065					
Other (mean regression value)	0.99513(1/x weighted)					
RECOVERY (as a %)						
High QC in (matrix)=	8 µmol/L	103.0%	Calculated as a % of the peak area observed for derivatised water standards			
Med QC in (matrix)=	4 µmol/L	110.1%				
Low QC in (matrix)=	1 µmol/L	110.8%				
Results with different sample amounts (results of QC evaluations) intra-assay						
LLOQ QC=	0.4 µmol/L	0.45	6.9%	0.41-0.49	0.013	
Low QC=	1 µmol/L	1.06	7.2%	0.91-1.11	0.031	
Med QC=	4 µmol/L	4.01	4.1%	3.84-4.03	0.068	
High QC=	8 µmol/L					
Results with different sample amounts (results of QC evaluations) inter-assay						
LLOQ QC=	n/a	n/a	n/a	n/a	n/a	
Low QC=	1 µmol/L	1.05	5.7%	0.91-1.15	0.024	
Med QC=	4 µmol/L	3.97	7.1%	3.53-4.54	0.115	
High QC=	8 µmol/L	8.1	6.6%	7.08-8.75	0.219	
STABILITY (assuming any degradation is linear):						
a) Room Temperature in Matrix (+/- %/24 hrs)		% maximum				
b) Freeze/thaw (+/-% /3 cycles)		% maximum				
c) Injector (+/- %/24 hrs)		% maximum				

PM3006635886

Source: https://www.industrydocuments.ucsf.edu/docs/fqcj0001